



6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 372

[EPA-HQ-TRI-2015-0011; FRL-9937-12-OEI]

RIN 2025-AA41

Addition of 1-Bromopropane; Community Right-to-Know Toxic Chemical Release

Reporting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is adding 1-bromopropane to the list of toxic chemicals subject to reporting under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA) of 1986 and section 6607 of the Pollution Prevention Act (PPA) of 1990. 1-Bromopropane has been classified by the National Toxicology Program in their 13th Report on Carcinogens as “reasonably anticipated to be a human carcinogen.” The EPA has determined that 1-bromopropane meets the EPCRA section 313(d)(2)(B) criteria because it can reasonably be anticipated to cause cancer in humans.

DATES: This final rule is effective November 30, 2015, and shall apply for the reporting year beginning January 1, 2016 (reports due July 1, 2017).

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA-HQ-TRI-2015-0011. All documents in the docket are listed on the <http://www.regulations.gov> website. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and

will be publicly available only in hard copy form. Publicly available docket materials are available electronically through <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Daniel R. Bushman, Environmental Analysis Division, Office of Information Analysis and Access (2842T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460; telephone number: 202-566-0743; fax number: 202-566-0677; email: bushman.daniel@epa.gov, for specific information on this notice. For general information on EPCRA section 313, contact the Emergency Planning and Community Right-to-Know Hotline, toll free at (800) 424-9346 (select menu option 3) or (703) 412-9810 in Virginia and Alaska or toll free, TDD (800) 553-7672, <http://www.epa.gov/superfund/contacts/infocenter/>.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Notice Apply to Me?

You may be potentially affected by this action if you manufacture, process, or otherwise use 1-bromopropane. Potentially affected categories and entities may include, but are not limited to:

| Category | Examples of Potentially Affected Entities |
|----------|---|
| Industry | <p>Facilities included in the following NAICS manufacturing codes (corresponding to SIC codes 20 through 39): 311*, 312*, 313*, 314*, 315*, 316, 321, 322, 323*, 324, 325*, 326*, 327, 331, 332, 333, 334*, 335*, 336, 337*, 339*, 111998*, 211112*, 212324*, 212325*, 212393*, 212399*, 488390*, 511110, 511120, 511130, 511140*, 511191, 511199, 512220, 512230*, 519130*, 541712*, or 811490*.</p> <p>*Exceptions and/or limitations exist for these NAICS codes.</p> <p>Facilities included in the following NAICS codes (corresponding to SIC codes other than SIC codes 20 through 39): 212111, 212112, 212113 (correspond to SIC 12, Coal Mining (except 1241)); or 212221, 212222, 212231, 212234, 212299 (correspond to SIC 10, Metal Mining (except</p> |

| | |
|--------------------|--|
| | 1011, 1081, and 1094)); or 221111, 221112, 221113, 221118, 221121, 221122, 221330 (Limited to facilities that combust coal and/or oil for the purpose of generating power for distribution in commerce) (corresponds to SIC 4911, 4931, and 4939, Electric Utilities); or 424690, 425110, 425120 (Limited to facilities previously classified in SIC 5169, Chemicals and Allied Products, Not Elsewhere Classified); or 424710 (corresponds to SIC 5171, Petroleum Bulk Terminals and Plants); or 562112 (Limited to facilities primarily engaged in solvent recovery services on a contract or fee basis (previously classified under SIC 7389, Business Services, NEC)); or 562211, 562212, 562213, 562219, 562920 (Limited to facilities regulated under the Resource Conservation and Recovery Act, subtitle C, 42 U.S.C. 6921 et seq.) (corresponds to SIC 4953, Refuse Systems). |
| Federal Government | Federal facilities |

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Some of the entities listed in the table have exemptions and/or limitations regarding coverage, and other types of entities not listed in the table could also be affected. To determine whether your facility would be affected by this action, you should carefully examine the applicability criteria in part 372 subpart B of Title 40 of the Code of Federal Regulations. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding "FOR FURTHER INFORMATION CONTACT" section.

II. Introduction

A. What is the Statutory Authority for this Final Rule?

This rule is issued under EPCRA section 313(d) and section 328, 42 U.S.C. 11023 *et seq.*.

EPCRA is also referred to as Title III of the Superfund Amendments and Reauthorization Act of 1986.

B. What is the Background for this Action?

Section 313 of EPCRA, 42 U.S.C. 11023, requires certain facilities that manufacture, process, or otherwise use listed toxic chemicals in amounts above reporting threshold levels to report their environmental releases and other waste management quantities of such chemicals annually. These facilities must also report pollution prevention and recycling data for such chemicals, pursuant to section 6607 of the PPA, 42 U.S.C. 13106. Congress established an initial list of toxic chemicals that comprised 308 individually listed chemicals and 20 chemical categories.

EPCRA section 313(d) authorizes the EPA to add or delete chemicals from the list and sets criteria for these actions. EPCRA section 313(d)(2) states that the EPA may add a chemical to the list if any of the listing criteria in Section 313(d)(2) are met. Therefore, to add a chemical, the EPA must demonstrate that at least one criterion is met, but need not determine whether any other criterion is met. Conversely, to remove a chemical from the list, EPCRA section 313(d)(3) dictates that the EPA must demonstrate that none of the listing criteria in Section 313(d)(2)(A)-(C) are met. The EPCRA section 313(d)(2)(A)-(C) criteria are:

- The chemical is known to cause or can reasonably be anticipated to cause significant adverse acute human health effects at concentration levels that are reasonably likely to exist beyond facility site boundaries as a result of continuous, or frequently recurring, releases.
- The chemical is known to cause or can reasonably be anticipated to cause in humans:
 - cancer or teratogenic effects, or
 - serious or irreversible—
 - reproductive dysfunctions,
 - neurological disorders,

- heritable genetic mutations, or
 - other chronic health effects.
- The chemical is known to cause or can be reasonably anticipated to cause, because of:
 - its toxicity,
 - its toxicity and persistence in the environment, or
 - its toxicity and tendency to bioaccumulate in the environment,a significant adverse effect on the environment of sufficient seriousness, in the judgment of the Administrator, to warrant reporting under this section.

The EPA often refers to the section 313(d)(2)(A) criterion as the “acute human health effects criterion;” the section 313(d)(2)(B) criterion as the “chronic human health effects criterion;” and the section 313(d)(2)(C) criterion as the “environmental effects criterion.”

The EPA published in the **Federal Register** of November 30, 1994 (59 FR 61432), a statement clarifying its interpretation of the section 313(d)(2) and (d)(3) criteria for modifying the section 313 list of toxic chemicals.

III. Summary of Proposed Rule

A. What chemical did the EPA propose to add to the EPCRA section 313 list of toxic chemicals?

As discussed in the proposed rule (80 FR 20189, April 15, 2015), the EPA proposed to add 1-bromopropane to the EPCRA section 313 list of toxic chemicals. 1-Bromopropane had been classified as “reasonably anticipated to be a human carcinogen” by the National Toxicology Program (NTP) in its 13th Report on Carcinogens (RoC) document. In addition, based on a review of the available production and use information, the EPA determined that 1-bromopropane is expected to be manufactured, processed, or otherwise used in quantities that would exceed the EPCRA section 313 reporting thresholds. The NTP is an interagency program

within the Department of Health and Human Services (DHHS) headquartered at the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). As part of the NTP's cancer evaluation work, it periodically publishes the RoC document which contains cancer classifications from the NTP's most recent chemical evaluations as well as the classifications from previous versions of the RoC. There is an extensive review process for the RoC which includes evaluations by scientists from the NTP, other Federal health research and regulatory agencies (including the EPA), and nongovernmental institutions. The RoC review process also includes external peer review and several opportunities for public comment.

B. What was the EPA's rationale for proposing to list 1-bromopropane?

As the EPA stated in the proposed rule (80 FR 20189, April 15, 2015), the NTP RoC document undergoes significant scientific review and public comment and mirrors the review the EPA has historically done to assess chemicals for listing under EPCRA section 313 on the basis of carcinogenicity. The conclusions regarding the potential for chemicals in the NTP RoC to cause cancer in humans are based on established sound scientific principles. The EPA believes that the NTP RoC is an excellent and reliable source of information on the potential for chemicals covered therein to cause cancer in humans. Based on the EPA's review of the data contained in the 13th NTP RoC (Reference (Ref.) 1) for 1-bromopropane, the Agency agreed that 1-bromopropane can reasonably be anticipated to cause cancer. Therefore, the EPA determined that the evidence was sufficient for listing 1-bromopropane on the EPCRA section 313 toxic chemical list pursuant to EPCRA section 313(d)(2)(B) based on the available carcinogenicity data for 1-bromopropane as presented in the 13th RoC (Ref. 2).

IV. What comments did the EPA receive on the proposed rule?

The EPA received four comments on the proposed rule to add 1-bromopropane to the EPCRA section 313 chemical list. Three of the comments were supportive of the EPA's proposed addition of 1-bromopropane while one commenter objected to the addition. The commenters that supported the proposed rule included two anonymous comments from the general public (Refs. 3 and 4) and a comment from the Halogenated Solvents Industry Alliance, Inc. (HSIA) (Ref. 5). Members of the HSIA include The Dow Chemical Company, INEOS Chlor Americas, Inc., Occidental Chemical, and Axiall Corporation. The commenter who objected to the addition was the Albemarle Corporation (Ref. 6). The most significant comments are summarized and responded to below. The complete set of comments and the EPA's responses can be found in the response to comment document in the docket for this rulemaking (Ref. 7). Note that in some of the comments 1-bromopropane is referred to as nPB, which is the acronym for the alternative chemical name n-propyl bromide.

The HSIA (Ref. 5) stated that the proposed rule presented substantial evidence to support the conclusion that 1-bromopropane is known to cause or can reasonably be anticipated to cause cancer in humans. The HSIA also noted that other published studies indicate that 1-bromopropane is neurotoxic, may cause reproductive dysfunction, and is acutely or chronically toxic. The HSIA concluded that clearly, the scientific literature supports the addition of 1-bromopropane to the list of chemicals subject to reporting under EPCRA section 313.

EPA agrees with the commenter's statement that the EPA provided substantial evidence to support the conclusion that 1-bromopropane is known to cause or can reasonably be anticipated to cause cancer in humans. The EPA also agrees with the commenter's conclusion that the scientific literature supports the addition of 1-bromopropane to the EPCRA section 313 chemical list. The EPA acknowledges that there may be other toxicological effects that may also

be a basis for listing. However, the EPA believes the available cancer data are sufficient for adding 1-bromopropane to the EPCRA section 313 chemical list.

The first anonymous commenter (Ref. 3) supported the addition of 1-bromopropane to the EPCRA section 313 list and cited additional toxicity information, neurotoxicity and reproductive toxicity, as being of concern.

EPA agrees that 1-bromopropane should be added to the EPCRA section 313 chemical list. The EPA also acknowledges that there may be other toxicological effects (such as neurotoxicity) that may also be a basis for listing. However, the available cancer data are sufficient for adding 1-bromopropane to the EPCRA section 313 chemical list.

The second anonymous commenter (Ref. 4) supported the listing of 1-bromopropane as long as the benefits substantially outweigh the costs. The commenter also expressed concern that there may be “significant costs to local businesses, i.e., laundry services, that have to update or replace their equipment as well as significant costs and time spent in order to comply with the rule.”

EPA’s cost-benefit analysis was contained in the economic analysis for the proposed rule “Economic Analysis of the Proposed Rule to add 1-Bromopropane to the EPCRA Section 313 List of Toxic Chemicals” (Ref. 8), which was reference 8 in the proposed rule (80 FR 20189, April 15, 2015). The economic analysis contains a quantitative estimate of the costs and a qualitative discussion of the benefits of the rule. The EPA considers the benefits of reporting under this rule to be primarily reflected by the purposes served by reporting of information under EPCRA section 313. The EPA believes the benefits provided by the information to be reported under this rule outweigh the costs.

With regard to laundry services (such as dry cleaners) these facilities are not subject to reporting under EPCRA section 313. Even if such facilities were subject to reporting, listing a chemical under EPCRA section 313 does not require covered facilities to update or replace any equipment. EPCRA section 313 only requires the reporting of release and waste management information, it does not impose any restrictions on the use of chemicals.

The majority of comments provided by the Albemarle Corporation (Ref. 6) are the same comments they submitted in response to the “Receipt of a complete petition” to add 1-bromopropane to the Hazardous Air Pollutant (HAP) List (80 FR 6676, February 6, 2015). The only comments submitted by the Albemarle Corporation specific to the EPA’s proposed rule to add 1-bromopropane to the EPCRA section 313 chemical list were provided in a letter from Charles R. Nestrud of the law firm Chisenhall, Nestrud & Julian, P.A. dated June 10, 2015 (Nestrud letter). The EPA is providing responses to all of the comments in the Nestrud letter.

The vast majority of the comments submitted by the Albemarle Corporation on the HAP listing petition dealt with issues of emissions, exposure, risk values, and risk assessment, which are not relevant to the proposed addition of 1-bromopropane to the EPCRA section 313 chemical list since the addition is based on hazard and not risk. The addition of 1-bromopropane to the EPCRA section 313 chemical list is based on the cancer hazard evaluation carried out by the NTP and reviewed by the EPA to ensure its consistency with the EPA Guidelines for Carcinogen Risk Assessment (Ref. 9). Consistent with the EPA guidelines (Ref. 9), the NTP 13th RoC (Ref. 2) evaluates the scientific literature and publicly available, peer-reviewed technical reports of human and laboratory studies to evaluate whether substances are possible human carcinogens. The NTP RoC does not present a quantitative assessment of the risks of cancer associated with a given chemical. Rather, it indicates the potential hazard associated with chemicals but does not

establish the exposure conditions that would pose cancer risks to individuals. In the 13th RoC, the NTP classified 1-bromopropane as “reasonably anticipated to be a human carcinogen.” The conclusions of the NTP 13th RoC for 1-bromopropane were consistent with how the EPA would consider the carcinogenicity data available for 1-bromopropane. Therefore, for the purposes of listing 1-bromopropane on the EPCRA section 313 chemical list, the EPA concluded that 1-bromopropane can reasonably be anticipated to cause cancer in humans. Since the listing of 1-bromopropane under EPCRA section 313 is based on the available cancer data, the EPA is not responding to the comments from Albemarle Corporation on the HAP listing petition that dealt with issues of emissions, exposure, risk values, and risk assessment.

While not specific to the materials the EPA cited to support the addition of 1-bromopropane to the EPCRA section 313 chemical list, there were some comments on the cancer data for 1-bromopropane in the materials that the Albemarle Corporation submitted in response to the HAP listing petition (Ref. 6). Specifically, these comments are contained in sections 2.2 and 2.3 of the document “Comments on the Petition to Add n-Propyl Bromide to the List of Hazardous Air Pollutants Regulated under § 112 of the Clean Air Act” prepared by the Gradient Corporation (Gradient Corp.). Since these comments dealt with the toxic endpoint (cancer) that is the basis for the addition of 1-bromopropane to the EPCRA section 313 chemical list, the EPA has addressed these comments as well.

In the Nestrud letter, the commenter stated that:

“The comments prepared by Albemarle and its consultants demonstrate that the technical information submitted to support the Proposed Rule is out of date, incorrect, and insufficient to support the Proposed Rule. Furthermore, when all toxicological data is

considered, and current emission data is considered, the weight of the evidence does not support adding 1-bromopropane to the list of toxic chemicals.”

EPA disagrees that the information submitted to support the proposed rule to add 1-bromopropane to the EPCRA section 313 chemical list is “out of date, incorrect, and insufficient to support the Proposed Rule.” The EPA provided information from the NTP 13th RoC which was released on October 2, 2014 (Ref. 2). The EPA’s evaluation of the data used to support the findings for 1-bromopropane was conducted shortly after the release of the 13th RoC and completed on November 3, 2014 (Ref. 1). The EPA’s economic analysis of the potential costs of the proposed rule including the estimate of the number of facilities expected to file reports was completed on February 17, 2015 (Ref. 8). The EPA notes that the commenter did not provide any comments specific to the EPA’s evaluation of the NTP 13th RoC data and findings for 1-bromopropane (Ref. 1), which was reference 6 in the proposed rule (80 FR 20189, April 15, 2015), or specific to the NTP 13th RoC materials prepared for 1-bromopropane (Refs. 10 and 11), which were references 5 and 7 in the proposed rule (80 FR 20189, April 15, 2015), or on the EPA’s economic analysis for the addition of 1-bromopropane (Ref. 8), which was reference 8 in the proposed rule (80 FR 20189, April 15, 2015). It is, therefore, unclear which technical information that the EPA submitted to support the proposed rule that the commenter believes is out of date, incorrect, or insufficient to support the proposed rule. Comments regarding the available cancer data and relevance of emissions data are discussed in other responses below.

The Nestrud letter also provided comments concerning screening criteria that the EPA had used in a previous rulemaking:

“In its 1994 rulemaking EPA identified certain criteria it had developed to evaluate chemicals for additions to the list of toxic chemicals. This included a toxicity and

production volume screen, and a hazard evaluation based on the initial screen. Addition of Certain Chemicals; Toxic Chemical Release Reporting; Community Right-to-Know; Final Rule (59 Fed. Reg. No. 229; Doc. No. 94-29376, November 30, 1994; OPPTS-400082B.

Toxicity Screen. Through the toxicity screen a chemical is assigned a "high priority," "medium priority," or "low priority." The attached comments submitted to EPA as part of the nPB Petition demonstrate that there is insufficient toxicity information to support assigning a "high priority," or "medium priority" to nPB.”

The information that the commenter cited regarding the criteria the EPA identified for evaluating chemicals for addition to the EPCRA section 313 chemical list are the criteria the EPA used for its 1994 chemical expansion rulemaking to evaluate large numbers of chemicals for potential addition. These screening criteria are not the criteria used to determine whether or not a chemical can be added to the EPCRA section 313 chemical list, that criteria is established under EPCRA section 313(d)(2). As the EPA noted in the 1994 chemical expansion rule:

“A toxicity screen is a limited review of readily available toxicity data that is used for a preliminary categorization of a chemical during the process of selecting candidates for possible listing under EPCRA section 313. The toxicity screen is used to identify chemicals for further consideration and does not reflect a final determination for listing a chemical under EPCRA section 313. Such a determination can only be made after a hazard assessment is conducted (See Unit 11.3. of this preamble).” (59 FR 61433, November 30, 1994)

EPA did not screen 1-bromopropane for addition, but rather conducted a hazard evaluation of the available cancer data and based on the classification by the NTP in their 13th

RoC as “reasonably anticipated to be a human carcinogen” and our review of that data, concluded 1-bromopropane should be added to the EPCRA section 313 chemical list. As noted in the proposed rule, the EPA reviewed the data used by the NTP to make this determination and agreed with the NTP’s classification (Ref. 1), which was reference 6 in the proposed rule (80 FR 20189, April 15, 2015). As the EPA noted in the 1994 chemical expansion rule, cancer is an extreme toxic effect:

“In some cases the effects are extreme, such as cancer or death.” (59 FR 61433, November 30, 1994)

If the EPA had conducted a toxicity screen like that used in the 1994 chemical expansion rule, the available cancer data would have been sufficient to classify 1-bromopropane as a high priority for listing. In fact, the NTP’s 6th RoC was a primary source reviewed for chemicals for potential addition (59 FR 1789, January 12, 1994). As previously noted, the commenter did not provide any comments specifically on the NTP’s classification of 1-bromopropane as “reasonably anticipated to be a human carcinogen” in the 13th RoC, nor did they provide any comments on the EPA’s evaluation of the NTP cancer data and classification (Ref. 1), as provided in reference 6 of the proposed rule (80 FR 20189, April 15, 2015).

The Nestrud letter also commented on the issue of a production volume screen:

“Production Volume Screen. When use of the chemical is less than the reporting thresholds, the chemical is "not considered further." The attached comments submitted to EPA as part of the nPB Petition demonstrate that there are no facilities in the dry cleaning or spray adhesives industries that use more 1-bromopropane than the reporting threshold of 10,000 pounds (5 tons). Although the nPB Petition identified one facility in the metal

cleaning industry that used more 1-bromopropane than the reporting threshold of 10,000 pounds (5 tons), that facility reported its use of nPB pursuant to its Title V Air Permit.”

Reference 8 in the proposed rule was the economic analysis for the addition of 1-bromopropane to the EPCRA section 313 chemical list (Ref. 8). As indicated in the economic analysis, the EPA estimates that 140 reports (126 Form Rs and 14 Form As) from 23 different industry sectors will be filed for 1-bromopropane. Therefore, the EPA has determined that there is sufficient production and use of 1-bromopropane such that reports will be filed. As previously noted, the commenter provided no specific comments on the EPA’s economic analysis. Certain spray adhesives industries may be required to report under EPCRA section 313, but dry cleaning facilities are not a covered industry sector and thus are not required to file reports under EPCRA section 313. While it has been the EPA’s policy to focus on the addition of chemicals for which reports are expected to be filed, it is not a statutory requirement. As the EPA noted in the 2010 proposed rule for the addition of 16 NTP carcinogens to the EPCRA section 313 chemical list:

“Section 313(d)(2) of EPCRA provides EPA the discretion to add chemicals to the TRI list when there is sufficient evidence to establish any of the listing criteria. EPA can add a chemical that meets one criterion regardless of its production volume.” (75 FR 17336, April 6, 2010)

The Nestrud letter also commented on the issue of conducting a hazard evaluation to support the listing of 1-bromopropane to the EPCRA section 313 list:

“**Hazard Evaluation.** Based on the results of the screen, EPA should conduct a Hazard Evaluation for 1-bromopropane. The attached comments submitted to EPA as part of the nPB Petition demonstrate that the weight of the evidence is not sufficient to add 1-bromopropane to the list of toxic chemicals. In particular, the individual lifetime cancer

risk at maximally impacted census receptors near the facilities that use 1-bromopropane is less than 1 in 1 million for all the facilities identified by EPA in the nPB Petition, with the exception of a narrow tube manufacturing facility, for which the maximum individual lifetime cancer risk is less than 1 in 100,000. Other than STC, there are no identified populations that would have a lifetime cancer risks from exposure to nPB in excess of 1 in 1 million.

Accordingly, there is no information that would support adding 1-bromopropane to the list of toxic chemicals.”

The commenter states that the EPA should conduct a “Hazard Evaluation” for 1-bromopropane, but that is exactly what the EPA did. The EPA’s hazard evaluation included the NTP’s classification of 1-bromopropane as “reasonably anticipated to be a human carcinogen” (Refs. 2 and 10) and the EPA’s review of the data used by the NTP to support that classification (Ref. 1). As noted in the proposed rule, the NTP conducted an extensive review (including public comment and peer review) of the cancer data for 1-bromopropane in making the classification for the NTP 13th RoC. The EPA’s review of that information, as discussed in reference 6 of the proposed rule, concluded that:

“The conclusions of the NTP RoC for 1-bromopropane were consistent with how the Agency would consider the carcinogenicity data available for 1-bromopropane.

Therefore, it would be appropriate for the Agency, for the purposes of listing 1-bromopropane on the Toxics Release Inventory, to conclude that 1-bromopropane can reasonably be anticipated to cause cancer in humans.” (80 FR 20189, April 15, 2015)

EPA believes the cancer data for 1-bromopropane sufficiently support listing under EPCRA section 313(d)(2)(B). None of the information concerning the cancer data that the

commenter submitted in their response to the petition to add 1-bromopropane to the hazardous air pollutant (HAP) list changes the EPA's conclusion with regard to the potential for 1-bromopropane to cause cancer in humans. Responses to the specific comments on certain portions of the hazard evaluation are addressed in other responses.

With regard to the commenter's conclusions concerning the cancer risks from facilities identified in the HAP petition, this information is not relevant to the addition of 1-bromopropane to the EPCRA section 313 chemical list. The EPA did not base the proposed addition of 1-bromopropane to the EPCRA section 313 chemical list on any exposure or risk evaluation. 1-Bromopropane meets the EPCRA section 313(d)(2)(B) listing criteria based on the cancer data alone and there are no statutory requirements to consider exposure or risk under EPCRA section 313(d)(2)(B). While the statutory criteria of EPCRA section 313(d)(2)(B) do not require consideration of exposure or risk, the EPA has a policy concerning when it may be appropriate to consider potential exposures when adding chemicals under EPCRA section 313(d)(2)(B). As the EPA stated in the proposed rule:

“EPA considers chemicals that can reasonably be anticipated to cause cancer to have moderately high to high chronic toxicity. EPA does not believe that it is appropriate to consider exposure for chemicals that are moderately high to highly toxic based on a hazard assessment when determining if a chemical can be added for chronic effects pursuant to EPCRA section 313(d)(2)(B) (see 59 FR 61440-61442). Therefore, in accordance with EPA's standard policy on the use of exposure assessments (59 FR 61432), EPA does not believe that an exposure assessment is necessary or appropriate for determining whether 1-bromopropane meets the criteria of EPCRA section 313(d)(2)(B).” (80 FR 20189, April 15, 2015)

The EPA disagrees with the conclusion of the commenter that there is no information that would support adding 1-bromopropane to the EPCRA section 313 chemical list. In fact, it is the EPA's position that there are extensive cancer data that support this addition as discussed and referenced in the proposed rule.

In the comments the Albemarle Corporation submitted on the HAP listing petition (Ref. 6), the report by Gradient Corp. included section "2.2 Human Relevance of the Petitioner's Inhalation Unit Risk Factor." In that section, issues regarding the cancer data for 1-bromopropane were raised. These issues include the petitioners' use of alveolar/bronchiolar adenomas and carcinomas in B6C3F1 mice for their risk assessment. The commenter took issue with the petitioners' suggestion that "there are no reasons to assume that the mode, or modes, of action by which tumors are induced by nPB are not relevant to man." The commenter stated that the petitioners' supporting information lacked an analysis of the human relevance of the mouse lung tumors or any other cancer endpoint and cited recommendations in the EPA's Guidelines for Carcinogen Risk Assessment for collecting relevant information on the mode of action. The commenter stated that alveolar/bronchiolar adenomas and carcinomas have been reviewed and debated for a number of chemical compounds and were the subject of a 2014 technical workshop sponsored by the EPA. The commenter also provided summaries of relevant information that they claim are available for 1-bromopropane to explore mode of action questions. The commenter concluded that there is evidence that the mode of action for the endpoint selected to predict risks for 1-bromopropane may not be relevant for humans. The commenter stated that, considering the state-of-the-science surrounding this health endpoint, the EPA should not rely on the data for alveolar/bronchiolar adenomas and carcinomas in B6C3F1 mice for characterizing cancer risks in humans from exposure to 1-bromopropane.

As the EPA previously noted, the proposed addition of 1-bromopropane to the EPCRA section 313 chemical list is based on hazard alone and not on any consideration of exposures or potential risks. For the purposes of listing under EPCRA section 313(d)(2)(B), the EPA is not relying on the data for alveolar/bronchiolar adenomas and carcinomas in B6C3F1 mice for characterizing cancer risks in humans from exposure to 1-bromopropane. While the EPA convened a technical workshop on the state-of-the-science for chemically-induced mouse lung tumors, there was no consensus on the relevance of this tumor to humans (Ref. 12). Rather, one of the workshop outcomes included the future application of the information discussed during the workshop to develop a mode of action framework on a chemical by chemical basis. As stated in the EPA Guidelines for Carcinogen Risk Assessment (Ref. 9):

“The default option is that positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans. Thus, if no adequate human or mode of action data are present, positive effects in animal cancer studies are a basis for assessing the carcinogenic hazard to humans.”

The NTP monograph for 1-bromopropane (Ref. 10) discussed the issue of mode of action in the section on mechanistic considerations:

“5.3 Mechanistic considerations

The biological events associated with chemically induced cancer are not completely understood even for chemicals that have been extensively studied and are known to cause cancer in humans (e.g., benzene and arsenic) (Guyton et al. 2009). It is important to recognize that chemicals can act through multiple toxicity pathways and mechanisms to induce cancer or other health effects, and the relative importance of the various pathways may vary with life stage, genetic background, and dose. Thus, it is unlikely that for any

chemical a single mechanism or mode of action will fully explain the multiple biological alterations and toxicity pathways that can cause normal cells to transform and ultimately form a tumor.

Although no studies were identified that were specifically designed to investigate possible modes of action for 1-bromopropane-induced carcinogenesis, the available data indicate that metabolic activation, genetic damage, and oxidative stress from glutathione depletion are important factors. As discussed in the previous section, these factors were linked to several of the primary non-neoplastic toxic effects of 1-bromopropane, including immunosuppression, neurotoxicity, reproductive toxicity, and hepatotoxicity. Other factors that have been associated with carcinogenesis and may be relevant for 1-bromopropane are discussed and include immune-response modulation, altered cell signaling and gene expression, inflammation, and cytotoxicity and compensatory cell proliferation.” (Ref. 10, page 40)

After considering the mode of action issues, the NTP classified 1-bromopropane as “reasonably anticipated to be a human carcinogen.” The EPA believes that this classification is consistent with how the data would be evaluated under the EPA’s Guidelines for Carcinogen Risk Assessment (Ref. 9).

In the comments the Albemarle Corporation submitted on the HAP listing petition, the report by Gradient Corp. included section “2.3 Human Relevance of NTP Results.” In that section, issues regarding the cancer data for 1-bromopropane were raised. The commenter stated that the petitioners cited NTP results for the mouse and rat bioassays as evidence of the potential carcinogenic activity of 1-bromopropane (Ref. 13). The commenter claims that the petitioner did not consider potential uncertainties that the commenter believes are found in the underlying

mutagenicity, genotoxicity, and carcinogenicity data for 1-bromopropane. The commenter claimed that this was not consistent with the EPA's cancer guidelines, which recommend evaluating the weight of evidence prior to determining the carcinogenic potential of a chemical substance. The commenter went on to summarize information from studies they believe show potential uncertainties that are apparent in the toxicological information for 1-bromopropane.

Since the publication of the NTP bioassay cited by the commenter (Ref. 13), the NTP published its 13th RoC (Ref. 2). In this report, the NTP concluded that there is sufficient evidence of carcinogenicity for 1-bromopropane based on (1) skin tumors in male rats, (2) tumors of the large intestine in female and male rats, and (3) lung tumors in female mice. The report also cited malignant mesothelioma of the abdominal cavity and pancreatic islet tumors in male rats and skin tumors (squamous-cell papilloma, keratoacanthoma, and basal-cell adenoma or carcinoma) in female rats as supporting evidence. The NTP's monograph for 1-bromopropane addresses all of the data issues that the commenter raised (Ref. 10).

According to the EPA's Guidelines for Carcinogen Risk Assessment (Ref. 9), an agent can be classified as "Likely to Be Carcinogenic to Humans" if it "has tested positive in animal experiments in more than one species, sex, strain, site, or exposure route, with or without evidence of carcinogenicity in humans." Inconsistencies between how the data were interpreted by the NTP and how that same data might be interpreted under the EPA's Guidelines for Carcinogen Risk Assessment (Ref. 9) were not identified (see reference 6 in the proposed rule). The EPA Guidelines for Carcinogen Risk Assessment reference the NTP criteria for assessing individual studies in the assessment of carcinogenicity, stating "(c)riteria for the technical adequacy of animal carcinogenicity studies have been published and should be used as guidance to judge the acceptability of individual studies, e.g., NTP, 1984..." (pages 2-16).

While the EPA acknowledges that uncertainties exist when evaluating any agent, the EPA agrees with NTP's assessment of the data and conclusions regarding the carcinogenicity of 1-bromopropane. Indeed, according to the EPA's Guidelines for Carcinogen Risk Assessment (Ref. 9) "The default option is that positive effects in animal cancer studies indicate that the agent under study can have carcinogenic potential in humans. Thus, if no adequate human or mode of action data are present, positive effects in animal cancer studies are a basis for assessing the carcinogenic hazard to humans." The EPA believes that the evaluation of the available data are consistent with the EPA's guidelines including the EPA's "Supplemental guidance for assessing susceptibility from early-life exposure to carcinogens (Final)" (Ref. 14).

The NTP in its monograph of 1-bromopropane (Ref. 10), which supported the 13th RoC listing (Ref. 2), concluded the following:

"Studies in vivo show that 1-bromopropane can covalently bind to protein in exposed rats and occupationally exposed workers. The available data provide some support that 1-bromopropane is genotoxic as it induced mutations in bacterial and mammalian cells and DNA damage in human cells. There is limited evidence that DNA damage was induced in leukocytes from 1-bromopropane-exposed workers. 1-Bromopropane did not induce chromosomal damage in exposed rodents (micronucleus induction assay) or gene-cell mutations (dominant lethal mutation assay). Several known or postulated metabolites of 1-bromopropane have been identified as mutagens and two, glycidol and propylene oxide (proposed), were shown to cause chromosomal and DNA damage in cultured mammalian cells. Both metabolites caused chromosomal damage in cells from rodents exposed in vivo, and propylene oxide induced DNA damage in cells from exposed workers. Three

other 1-bromopropane metabolites (α -bromohydrin, 3-bromo-1-propanol, and 1-bromo-2-propanol) were mutagenic or caused DNA damage in bacteria.”

The EPA agrees with the NTP’s conclusions regarding the mutagenicity of 1-bromopropane and its metabolites. With the exception of the summary information provided by the commenter for one unpublished study, all of the studies cited by the commenter in their assessment of the mutagenicity data for 1-bromopropane were cited by the NTP in their monograph for 1-bromopropane (Ref. 10). Also, the commenter focused on the mutagenicity data for 1-bromopropane, but the data on the mutagenicity of the metabolites of 1-bromopropane are an important part of the assessment as well. The summarized results of the unpublished study provided by the commenter do not change the conclusion regarding the mutagenicity of 1-bromopropane and its metabolites.

V. Summary of Final Rule

The EPA is finalizing the addition of 1-bromopropane to the EPCRA section 313 list of toxic chemicals. The EPA has determined that 1-bromopropane meets the listing criteria under EPCRA section 313(d)(2)(B) based on the available carcinogenicity data.

VI. References

The EPA has established an official public docket for this action under Docket ID No. EPA-HQ-TRI-2015-0011. The public docket includes information considered by the EPA in developing this action, including the documents listed below, which are electronically or physically located in the docket. In addition, interested parties should consult documents that are referenced in the documents that the EPA has placed in the docket, regardless of whether these referenced documents are electronically or physically located in the docket. For assistance in locating documents that are referenced in documents that the EPA has placed in the docket, but

that are not electronically or physically located in the docket, please consult the person listed in the above FOR FURTHER INFORMATION CONTACT section. For convenience, the docket also includes all of the **Federal Register** documents cited in this action.

1. USEPA, OEI, 2014. Memorandum from Jocelyn Hospital, Toxicologist, Analytical Support Branch to Sandra Gaona, Acting Chief, Analytical Support Branch. November 3, 2014. Subject: Review of National Toxicology Program (NTP) Cancer Classification Data for 1-bromopropane.

2. NTP, 2014. National Toxicology Program. Report on Carcinogens, Thirteenth Edition. Released October 2, 2014. U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, Research Triangle Park, NC 27709.
(<http://ntp.niehs.nih.gov/pubhealth/roc/roc13/index.html>)

3. Anonymous public comment. April 15, 2015. EPA-HQ-TRI-2015-0011-0048.

4. Anonymous public comment. April 16, 2015. EPA-HQ-TRI-2015-0011-0049.

5. Comment submitted by Faye Gaul, Executive Director, Halogenated Solvents Industry Alliance Incorporated (HSIA). Re: Docket ID No. EPA-HQ-TRI-2015-0011. June 15, 2015. EPA-HQ-TRI-2015-0011-0051.

6. Comment submitted by Niomi Krzystowczyk, Vice President, Health, Safety and Environment, Albemarle Corporation. Re: Proposed Rule: Addition of 1-Bromopropane; Community Right-to-Know Toxic Chemical Release Reporting; Docket ID No. EPA-HQ-TRI-2015-0011 [FRL-9925-29-OEI, 80 Fed. Reg. 20189 (April 15, 2015)]. June 10, 2015. EPA-HQ-TRI-2015-0011-0050.

7. USEPA, OEI, 2015. Response to Comments Received on the April 15, 2015, Federal Register Proposed Rule (80 FR 20189): Addition of 1-Bromopropane; Community Right-to-Know Toxic Chemical Release Reporting. U.S. Environmental Protection Agency Office of Environmental Information, Office of Information Analysis and Access. August 20, 2015.

8. USEPA, OEI, 2015. Economic Analysis of the Proposed Rule to add 1-Bromopropane to the EPCRA Section 313 List of Toxic Chemicals. February 17, 2015.

9. USEPA, 2005. Guidelines for Carcinogen Risk Assessment. Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, DC, March 2005. EPA/630/P-03/001F.

10. NTP, 2013. Report on Carcinogens Monograph on 1-Bromopropane. Office of the Report on Carcinogens, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, U.S. Department of Health and Human Services. NIH Publication No. 13-5982, September 25, 2013.

11. NTP, 2014. National Toxicology Program. Report on Carcinogens, Thirteenth Edition, Profile for 1-Bromopropane. Released October 2, 2014. U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program, Research Triangle Park, NC 27709.

12. USEPA, 2014. Summary Report of the State-of-the-Science Workshop on Chemically-induced Mouse Lung Tumors: Applications to Human Health Assessments. National Center for Environmental Assessment, Washington, DC, December 2014. EPA/600/R-14/002.

13. NTP, 2011. Technical Report on the Toxicology and Carcinogenesis Studies of 1-Bromopropane (CAS No. 106-94-5) in F344/N Rats and B6C3F1 Mice (Inhalation Studies).

Toxicity Report Series No. 564. NIH Publication No. 11-5906. Department of Health and Human Services, Public Health Service, Research Triangle Park, NC.

14. USEPA, 2005. Supplemental guidance for assessing susceptibility from early-life exposure to carcinogens (Final). Risk Assessment Forum, Washington, DC, March 2005. EPA/630/R-03/003F.

VII. What are the Statutory and Executive Order reviews associated with this action?

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was therefore not submitted to the Office of Management and Budget (OMB) for review.

B. Paperwork Reduction Act

This action does not contain any new information collection requirements that require additional approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). OMB has previously approved the information collection activities contained in the existing regulations and has assigned OMB control numbers 2025-0009 and 2050-0078. Currently, the facilities subject to the reporting requirements under EPCRA 313 and PPA 6607 may use either the EPA Toxic Chemicals Release Inventory Form R (EPA Form 1B9350-1), or the EPA Toxic Chemicals Release Inventory Form A (EPA Form 1B9350-2). The Form R must be completed if a facility manufactures, processes, or otherwise uses any listed chemical above threshold quantities and meets certain other criteria. For the Form A, the EPA established an alternative threshold for facilities with low annual reportable amounts of a listed

toxic chemical. A facility that meets the appropriate reporting thresholds, but estimates that the total annual reportable amount of the chemical does not exceed 500 pounds per year, can take advantage of an alternative manufacture, process, or otherwise use threshold of 1 million pounds per year of the chemical, provided that certain conditions are met, and submit the Form A instead of the Form R. In addition, respondents may designate the specific chemical identity of a substance as a trade secret pursuant to EPCRA section 322, 42 U.S.C. 11042, 40 CFR part 350.

OMB has approved the reporting and recordkeeping requirements related to Forms A and R, supplier notification, and petitions under OMB Control number 2025-0009 (EPA Information Collection Request (ICR) No. 1363) and those related to trade secret designations under OMB Control 2050-0078 (EPA ICR No. 1428). As provided in 5 CFR 1320.5(b) and 1320.6(a), an Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers relevant to the EPA's regulations are listed in 40 CFR part 9, 48 CFR chapter 15, and displayed on the information collection instruments (e.g., forms, instructions).

C. Regulatory Flexibility Act (RFA), as Amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 et seq.

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are small manufacturing facilities. The Agency has determined that of the 140 entities estimated to be impacted by this action, 136 are small businesses; no small governments or small organizations are expected to be affected by this action. All 136 small businesses affected by this action are estimated to incur annualized cost impacts of less than 1%. Facilities eligible to use Form A (those meeting the appropriate activity threshold which have 500 pounds per year or

less of reportable amounts of the chemical) will have a lower burden. Thus, this action is not expected to have a significant adverse economic impact on a substantial number of small entities. A more detailed analysis of the impacts on small entities is located in the EPA's economic analysis support document (Ref. 8).

D. Unfunded Mandates Reform Act

This action does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action is not subject to the requirements of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. Small governments are not subject to the EPCRA section 313 reporting requirements. The EPA's economic analysis indicates that the total cost of this action is estimated to be \$531,002 in the first year of reporting (Ref. 8).

E. Executive Order 13132 (Federalism)

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. This action relates to toxic chemical reporting under EPCRA section 313, which primarily affects private sector facilities. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. The results of this evaluation are contained below.

This action does not address any human health or environmental risks and does not affect the level of protection provided to human health or the environment. This action adds an additional chemical to the EPCRA section 313 reporting requirements. By adding a chemical to the list of toxic chemicals subject to reporting under section 313 of EPCRA, the EPA would be providing communities across the United States (including minority populations and low income populations) with access to data which they may use to seek lower exposures and consequently

reductions in chemical risks for themselves and their children. This information can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment. Therefore, the informational benefits of the action will have a positive impact on the human health and environmental impacts of minority populations, low-income populations, and children.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 372

Environmental protection, Community right-to-know, Reporting and recordkeeping requirements, and Toxic chemicals.

Dated: November 9, 2015.

Gina McCarthy,
Administrator.

For the reasons set forth in the preamble, the EPA amends 40 CFR part 372 as follows:

PART 372—TOXIC CHEMICAL RELEASE REPORTING: COMMUNITY RIGHT-TO-KNOW

1. The authority citation for part 372 continues to read as follows:

Authority: 42 U.S.C. 11023 and 11048.

2. In § 372.65, paragraph (a) is amended by adding in the table the entry for “1-Bromopropane” in alphabetical order and in paragraph (b) by adding in the table the entry for “106-94-5” in numerical order to read as follows:

§ 372.65 Chemicals and chemical categories to which this part applies.

* * * * *

(a) * * *

| Chemical name | CAS No. | Effective date |
|----------------|----------|----------------|
| * * * * * | | |
| 1-Bromopropane | 106-94-5 | 1/1/16 |
| * * * * * | | |

* * * * *

(b) * * *

| CAS No. | Chemical name | Effective date |
|-----------|----------------|----------------|
| * * * * * | | |
| 106-94-5 | 1-Bromopropane | 1/1/16 |
| * * * * * | | |

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[FR Doc. 2015-29799 Filed: 11/20/2015 8:45 am; Publication Date: 11/23/2015]